UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA ex rel. GREGORY M. GOODMAN,	)	
Plaintiff,	)	
v.	)	**Case No. 3:13-cv-0760**
	)	**Judge Aleta A. Trauger**
ARRIVA MEDICAL, LLC, ALERE, INC., TED ALBIN, and GRAPEVINE BILLING AND CONSULTING SERVICES, INC.,	)	
Defendants.	)	

MEMORANDUM & ORDER

The United States has filed a Motion for Review (Docket No. 158) of the magistrate judge's nondispositive Order of May 18, 2020 (Docket No. 154), to which Arriva Medical, LLC ("Arriva") and Alere, Inc. ("Alere") have filed a Response (Docket No. 170), and the government has filed a Reply (Docket No. 173). For the reasons set out herein, that motion will be granted in part and denied in part.

I. BACKGROUND

A. The False Claims Act and the Anti-Kickback Statute

"Since its enactment . . . , the False Claims Act"—often referred to as the "FCA"—"has authorized both the Attorney General and private *qui tam* relators to recover from persons who make false or fraudulent claims for payment to the United States." *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 (2010). A "claim," as defined by the Act, is "any request or demand . . . for money or property . . . that . . . (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient,

if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest," with the caveat that certain additional requirements must be met for this second type of claim, made to an intermediary. 31 U.S.C. § 3729(b)(2). Because systems of government payment are various and often complex, Congress has, over the years, set forth a number of different ways in which an individual or entity can incur liability under the FCA, some of which do not even expressly refer to a "false claim" at all, and others of which allow the underlying claim to be false *or* fraudulent. Specifically, a person or company violates the Act if he

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property; (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true; (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . .

31 U.S.C. § 3729(a)(1).

As the court has previously observed in this case, one of the areas in which the FCA has grown to play a major role is in combating fraud within the federal healthcare programs that now account for a substantial portion of federal non-defense expenditures. The FCA, however, is not the only statute safeguarding those programs. Another such statute, the Anti-Kickback Statute, or "AKS," "prohibits 'knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or

kind, . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.'" *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015) (quoting 42 U.S.C. § 1320a–7b(b)(1)(A)).

Some AKS violations are obvious; for example, if a hospital CEO "paid kickbacks to physicians who referred Medicare and Medicaid patients to" his hospital, then he probably violated the AKS. *United States v. Novak*, No. 17 C 4887, 2018 WL 4205540, at *1 (N.D. Ill. Sept. 4, 2018). Other forms of AKS violation, however, involve types of remuneration that might not, at first blush, strike a layperson as problematic. One such type of violation is at issue in this case: waivers of Medicare copayments and deductibles. Medicare, like ordinary insurers, frequently requires patients to shoulder a portion of the costs of their treatment. Some healthcare providers, however, have concluded that it is better for business just to waive the patient's share, which is typically smaller and more difficult to collect, and rely solely on the Medicare portion of the payment. The waived balance then serves as an enticement for the patient to choose that healthcare provider, on the ground that the services are effectively free to him. Such enticements, however, have been held by courts to be violations of the AKS, because they amount to paying someone to choose one provider over another. *See, e.g., United States v. Crescendo Bioscience, Inc.*, No. 16-CV-02043-TSH, 2020 WL 2614959, at *10 (N.D. Cal. May 23, 2020); *United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, No. CV 9:14-230-RMG, 2017 WL 5033652, at *2 (D.S.C. Oct. 31, 2017). Federal regulations embrace this reading, setting forth limited exceptions for certain situations in which waivers of deductibles are permissible but otherwise treating the waivers as violations of the AKS. *See* 42 C.F.R. § 1001.952(k).

The AKS "is a criminal statute, and does not," by its own terms, "create a private right of action." *United States ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2019 WL 1245656, at *5 (S.D.N.Y. Feb. 27, 2019) (citing *Donovan v. Rothman*, 106 F. Supp. 2d 513, 516 (S.D.N.Y. 2000)). Over the years, however, the United States and *qui tam* relators developed a practice of pursuing civil FCA claims in which an AKS violation was the "FCA predicate." *U.S. ex rel. Wheeler v. Union Treatment Centers, LLC*, No. CV SA-13-CA-4-XR, 2019 WL 571349, at *5 (W.D. Tex. Feb. 12, 2019). The logic of these cases, which many courts embraced, was that AKS compliance is a requirement for providing services under federal healthcare programs, and, therefore, submitting claims for payment when one was in knowing violation of the AKS amounted to fraudulently seeking a payment to which one was not entitled. *See U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) ("Legion other cases have held violations of AKS . . . can be pursued under the FCA, since they would influence the Government's decision of whether to reimburse Medicare claims.") (collecting cases).

Whether courts were correct in linking the FCA and AKS in early cases may have been debatable; at the very least, that linkage did not expressly appear in either statute. In 2010, however, Congress, "as part of the Patient Protection and Affordable Care Act ('PPACA'), . . . amended the AKS by adding the following language: 'In addition to the penalties provided for in this section . . . , a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31,' i.e., the FCA."*Arnstein*, 2019 WL 1245656, at *5 (quoting 42 U.S.C. § 1320a-7b(g)). As a result, the term "false or fraudulent claim," under the FCA, is defined, as a matter of law, to encompass any "claim that includes items or services resulting from" an AKS violation. Since the AKS revision in the PPACA went into effect, therefore, the premise that one can support an FCA claim with an

AKS violation has been a creature of statutory text, not merely judicial construction or administrative guidance.

B. This Litigation

Until it ceased operations in December 2017, Arriva sold diabetes supplies, such as glucose meters and test strips, to Medicare beneficiaries. From 2011 until late 2017, Arriva was owned by Alere, and now both entities are owned by Abbott Laboratories. (Docket No. 121 ¶ 1.) On August 1, 2013, an Arriva employee, Gregory M. Goodman, filed an FCA Complaint against Arriva and Alere. (Docket No. 1 ¶ 4.) He accused the companies of "six distinct but related schemes to defraud the federal government." (*Id.* ¶ 11.) Among Goodman's allegations was that the defendants improperly waived or forgave Medicare Part B patients' copayment and deductible obligations in violation of the AKS. (*Id.* ¶¶ 7, 13, 41.) Goodman also alleged that Arriva/Alere routinely billed for glucose meters that it knew were likely to be disallowed under Medicare because the program had already paid for a glucose meter for that patient in the last five years, which, according to the so-called "five-year rule," made the patient ineligible for a new meter. (*Id.* ¶¶ 68, 121.)

In the years following Goodman's filing of his Complaint, the government received a number of *ex parte* extensions of the seal and the window for intervention, in order to allow it to pursue its investigation of the defendants.[1] (*See, e.g.*, Docket Nos. 21, 29, 36, 40, 44, 48, 52, 66.) On May 14, 2019, the government filed a Complaint-in-Intervention, which was followed by an Amended Complaint-in-Intervention on August 1, 2019. (Docket Nos. 76 & 102.) The government

[1] A *qui tam* complaint under the FCA "shall be filed *in camera*, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders." 31 U.S.C. § 3730(b)(2). "The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal . . . ." 31 U.S.C. § 3730(b)(3). Eventually, however, the government must either inform the court that it wishes to "proceed with the action" or it must "notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4)(A)–(B).

alleges both that the defendants submitted false claims resulting from AKS violations and that they submitted claims that are actionable under the FCA for other reasons, namely because the relevant patients were dead on the alleged dates of service or because, as Goodman had alleged, Arriva routinely violated the five-year rule. (*Id.* ¶¶ 358, 388.) Count I of the Amended Complaint-in-Intervention is an FCA claim based on the submission of false claims to Medicare, pursuant to 31 U.S.C. § 3729(a)(1)(A). Count II is a claim based on the making or using of false records that are material to a false or fraudulent Medicare claim, pursuant to 31 U.S.C. § 3729(a)(1)(B). Count III is for conspiracy under the FCA, pursuant to 31 U.S.C. § 3729(a)(1)(C). Counts IV and V are, respectively, for unjust enrichment and payment by mistake. (*Id.* ¶¶ 391–419).

On February 21, 2020, the parties filed a Joint Discovery Dispute Statement (Docket No. 139), setting forth three discovery-related issues on which they had come to an impasse. Issue 3 involved interrogatories, from the defendants to the government, "asking the government to identify other suppliers that engaged in practices similar to those alleged in the complaint." (*Id.* at 2.) The defendants also asked the government to "admit it knew that other suppliers engaged in those practices" and to provide "documents and communications concerning other suppliers that engaged in practices similar to those alleged in the complaint and the government's knowledge of those practices." (*Id.*) The purpose of the defendants' requests was to reveal whether the Medicare program actually, as a matter of practice, treats actions like Arriva's as grounds for refusing to pay Medicare claims. If the discovery revealed that Medicare does not actually take such a harsh view toward similar violations, the defendants would present that fact to contest whether any actual fraud occurred. (*Id.* at 18.)

The government opposed the defendants' request, arguing that the requested information would be expensive and onerous to gather and that the issue of materiality is not, in its view,

genuinely contestable in this case. (*Id.* at 28.) The government argued that aspects of the request would effectively require the government to perform a full-scale investigation of every other diabetes testing supplier. For example, the defendants asked the government to do the following:

> Identify all Diabetes Testing Supply providers that have offered free Diabetes Testing Supplies or products to Medicare patients, including for each (i) the identity of the provider; (ii) the Diabetes Testing Supply or product provided; (iii) the number of free products that they supplied; (iv) when the free products were supplied; and (v) whether CMS reimbursed subsequent claims that each provider submitted for Diabetic Testing Supplies provided to the Medicare beneficiaries who received free supplies.

(*Id.* at 42–43.) The government argued that that request would transform this already-unwieldy case involving one supplier into an almost impossibly complex investigation of *every* supplier. (*Id.* at 43.)

The court referred the dispute to the magistrate judge, who held a hearing on the matter on March 9, 2020. Aside from the Joint Discovery Dispute Statement, no other substantive written briefing was filed prior to the magistrate judge's decision. On May 8, 2020, the magistrate judge entered an Order addressing the disputes. (Docket No. 154.) The magistrate judge acknowledged the government's arguments that materiality had been established as a matter of law but cautioned that, "[w]hether information obtained in discovery can prove lack of materiality or whether materiality is proven as a matter of law are issues to be decided at an appropriate point in this litigation, not during a discovery dispute." (*Id.* at 5.) Because the information sought therefore might be determinative of materiality, the magistrate judge concluded that it was relevant. With regard to the government's argument that the burden of producing the information was disproportionate to the relevance, the court held that, based on the materials before her at the time, the burden on the defendants did not justify rejecting the discovery request outright. The magistrate

judge did, however, conclude that the defendants' request should be limited to 25 specific diabetes testing suppliers that had been identified as a potential compromise by the defendants. (*Id.* at 6.)

On June 8, 2020, the government filed a Motion to Review the Order (Docket No. 158), which the defendants oppose (Docket No. 170). In support of its motion, the government has submitted evidence—which was not provided to the magistrate judge—suggesting that the "process for the United States to search for and review for responsiveness, confidentiality, and privilege documents regarding the 25 identified suppliers from five Medicare contractors would take at least 6,100 to 8,200 hours (and likely more) of manual review of over 1,800 investigative files, costing approximately $500,000 or more." (Docket No. 159 at 3; *see* Docket Nos. 160–66 (Declarations of relevant personnel).)

II. LEGAL STANDARD

While a *de novo* standard of review applies to objections to a magistrate judge's ruling on a dispositive matter, this court's review of a magistrate judge's resolution of a nondispositive pretrial matter is limited to determining whether the order is "clearly erroneous" or "contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); *see also Massey v. City of Ferndale*, 7 F.3d 506, 509 (6th Cir. 1993) ("When a magistrate judge determines a non-excepted, pending pretrial matter, the district court has the authority to 'reconsider' the determination, but under a limited standard of review."). "A finding [of fact] is 'clearly erroneous' when[,] although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Adams Cty. Reg'l Water Dist. v. Vill. of Manchester*, 226 F.3d 513, 517 (6th Cir. 2000) (quoting *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)). A legal conclusion is contrary to law if it "contradict[s] or ignore[s] applicable precepts of law, as

found in the Constitution, statutes, or case precedent. *Gandee v. Glaser*, 785 F. Supp. 684, 686 (S.D. Ohio 1992) (quoting *Adolph Coors Co. v. Wallace*, 570 F. Supp. 202, 205 (N.D. Cal.1983)).

III. ANALYSIS

A. Materiality, Conditions of Payment, and *Escobar*

As the FCA's lengthy set of provisions establishing grounds for liability can attest, Congress, the courts, and litigants have, over the Act's long existence, explored many different types of fraud against the government as predicates for liability. One such type of alleged fraud arises when a vendor for a government program provides a good or service for which he would generally be entitled to payment, but he does so in a way that violates some other, non-FCA law; prior to the PPACA, for example, AKS-based claims were of this variety. Courts in the Sixth Circuit have historically dealt with FCA claims based on violations of non-FCA laws through the lens of "conditions of payment" and "implied certification." *See, e.g., United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 826 (6th Cir. 2018) (describing false certification theory of FCA liability); *Ickes v. Nexcare Health Sys., LLC*, No. 13-14260, 2014 WL 12650930, at *2–3 (E.D. Mich. Aug. 4, 2014) (discussing caselaw regarding conditions of payment). According to this framework, a Medicare provider who submits a claim impliedly certifies compliance with all laws that are "conditions of payment"—that is, all laws that would lead Medicare to deny the claim if it knew about a violation.[2] *See U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013). Accordingly, the claim, though not expressly false on its face, is impliedly false in a manner material to payment or nonpayment of the claim. *Id.*

[2] Conditions of payment are sometimes contrasted with "conditions of participation"—requirements for participation in the relevant healthcare program that nevertheless are not treated as preconditions for payment of any individual claim. "Of course, a regulation may in some cases be both a condition of payment and a condition of participation." *Hobbs*, 711 F.3d at 714. Only a claim tainted by a false certification about a condition of payment, however, would be a false claim. *Id.*

Courts and litigants have struggled at times with the implied certification/conditions of payment framework or even rejected that framework altogether. In particular, the various circuit courts found considerable disagreement with regard to the types of evidence or legal grounds that were sufficient (or required) to establish that a particular non-FCA legal requirement could support an implied false certification claim—if such a theory was even available at all. *Compare United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711–12 (7th Cir. 2015) ("Although a number of other circuits have adopted this so-called doctrine of implied false certification, we decline to join them" (footnote omitted)) *with Mikes v. Strauss*, 274 F.3d 687, 702 (2d Cir. 2001) (allowing implied false certification claims, but only with regard to requirements expressly identified as conditions of payment) *with United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) ("The existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not . . . a necessary condition.").

Recognizing that disagreement among the lower courts, the Supreme Court stepped in to clarify matters in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). The defendant in *Escobar* had sought payment under the Medicaid program for mental health services, despite allegedly having been out of compliance with a number of licensing, qualifications, and supervision requirements. Under the care of these unlicensed, unqualified, and/or inadequately supervised individuals, a teenage patient died, allegedly from her reaction to prescribed medication. After the deceased patient's parents learned of the defendant's alleged deficiencies, they brought an FCA suit. *Id.* at 1997. The First Circuit held that, based on the "express and absolute language" of the relevant regulations, which that court considered "dispositive," the regulations were conditions of payment sufficient to give rise to FCA liability.

U.S. ex rel. Escobar v. Universal Health Servs., Inc., 780 F.3d 504, 514 (1st Cir. 2015). In other words, the First Circuit treated the question of whether a regulation can form the predicate of an FCA claim as an issue resolvable by looking solely at its text and the text of any relevant program rules, at least where the rules' status as conditions of payment is explicit.

The defendant appealed, and the Supreme Court vacated the decision below—not because the Court concluded that the regulations categorically were *not* conditions of payment, but because the Court disagreed with the First Circuit's purely text-based approach. The Court agreed, as an initial matter, that, contrary to some courts' conclusions, "the implied false certification theory can be a basis for liability" under the FCA. *Escobar*, 136 S. Ct. at 1995. The Court concluded, however, that liability "does not turn upon whether those requirements were expressly designated as conditions of payment." *Id.* at 1996. Rather, "[w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.*

The court observed, however, that its discussion of materiality revealed a textual quirk of the FCA: that materiality is an *explicit, defined* element with regard to one of its most commonly relied upon grounds for liability, but is merely an *implied* element with regard to another. *Id.* Specifically, 31 § U.S.C. 3729(a)(1)(B) attaches liability to any instance where a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." That use of the word "material" is subject to the FCA's statutory definition of the term, "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). However, the Supreme Court also recognized that 31 U.S.C. § 3729(a)(1)—which imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"— has its

own implicit materiality requirement, despite "material" not appearing in the subsection. *Escobar*, 136 S. Ct. at 2002 (referring to "§ 3729(a)(1)(A)'s materiality requirement"); *cf. Brookdale Senior Living*, 892 F.3d at 830 (describing materiality as a general requirement for any FCA claim). The materiality requirement of 31 U.S.C. § 3729(a)(1), rather, arises from reading the phrase "false or fraudulent claim" in the context of its "common-law antecedents" defining the principles of the law of fraud. *Id.* (quoting *Kungys v. United States*, 485 U.S. 759, 769 (1988)).

As the Court noted, implied certification is a form of fraud by omission, and an omission can only render a statement false if the omitted fact is material to the statement, such that leaving that fact out renders the claim a "misleading half-truth[]." *Id.* at 2001. A claim that merely omits an immaterial fact cannot be false or fraudulent, because there would be no reason for the listener to expect the fact to be included. *Id.* The "false or fraudulent claim" requirement of 31 U.S.C. § 3729(a)(1) therefore brought with it its own materiality requirement. With regard to how the materiality requirements compared to each other, the Court concluded that, whether or not the express statutory definition of "material" applied to implied materiality under 31 U.S.C. § 3729(a)(1), the definition would be largely the same. *Escobar*, 136 S. Ct. at 2002–03.

Finally, the Court explained some of the ways that the government or a *qui tam* relator can satisfy the "demanding" requirements of the FCA "materiality standard." *Id.* at 2003. The court reiterated that "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* The court added that it also is not "sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Although those facts would be relevant, the issue of materiality, as defined in *Escobar*, looks more deeply into the actual practices of the government entity at issue:

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04. The examples provided by the Supreme Court in *Escobar* contrast starkly with the text-focused approach taken by the circuit court below. The language of the relevant provisions is still relevant under *Escobar*, but just as important is how the regulation is actually treated by the federal program at issue. In other words, under *Escobar*, materiality is better demonstrated in both the government's words and its deeds , rather than through its words alone. *See Brookdale Senior Living*, 892 F.3d at 831 (describing the materiality inquiry under *Escobar* as "holistic") (quoting *United States ex rel. Escobar v. Universal Health Servs.*, Inc., 842 F.3d 103, 109 (1st Cir. 2016) (following remand)).

B. Relevance of Requested Discovery to AKS-Based FCA Claims

Rule 26(b)(1) of the Federal Rules of Civil Procedure provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense," as long as the discovery requested is "proportional to the needs of the case." Relevance, as the concept is used in Rule 26(b)(1), "has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (citing *Hickman v. Taylor*, 329 U.S. 495, 501 (1947)); *accord Marsico v. Sears Holding Corp.*, 370 F. App'x 658, 664 (6th Cir. 2010). The defendants argue that the information they have requested bears on the question of whether the alleged AKS violations they committed were material to payment under the

Medicare program under *Escobar*. The government responds that materiality is not reasonably in dispute in this case and that, therefore, the information sought is either wholly irrelevant or of such minimal relevance that the hardship of the discovery would outweigh its value.

There can be little doubt that, if *Escobar* squarely governed the government's AKS-based claims, the information sought would be relevant. *Escobar* made clear that the government's treatment of other similarly situated healthcare providers is relevant to the issue of materiality in an FCA healthcare case. The government, moreover, cannot merely rely on the fact that the AKS is an important statute that has historically been held to support FCA liability in other cases. The *Escobar* materiality inquiry looks not only to the broad statute, rule, or contract cited, but also to the specific type of violation at issue, on the premise that "[m]ateriality . . . cannot be found where noncompliance is minor or insubstantial." 136 S.Ct. at 2003. The type of violation at issue must "go[] 'to the very essence of the bargain'" between the healthcare provider and the relevant federal healthcare program in order to be material. *Brookdale Senior Living*, 892 F.3d at 834 (quoting *Escobar*, 136 S.Ct. at 2003 n.5). Therefore, even if one assumed that it is settled law that AKS violations *can* support FCA claims, that would not, in and of itself, resolve the question of whether the particular practices at issue in this case would constitute violations substantial enough to be material.

The only legal obstacle potentially standing between the defendants and challenging materiality pursuant to *Escobar*, then, is 42 U.S.C. § 1320a-7b(g), the provision of the PPACA directing that a "claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the FCA. The defendants argue that that provision has no bearing on the *Escobar* framework because it makes no mention of materiality, only falsity or fraudulence. Accordingly, while 42 U.S.C. § 1320a-7b(g) would make the issue of

falsity beyond dispute in an AKS-based FCA case, the issue of materiality would remain open. Section 1320a-7b(g), however, does not say that a claim caused by an AKS violation is false; it says that such a claim, as a matter of law, "constitutes a false or fraudulent claim."

As the Supreme Court explained in its discussion of 31 U.S.C. § 3729(a)(1)(A) in *Escobar*, the materiality requirement in that provision is read into the phrase "false or fraudulent claim," because materiality is a requirement for fraud at common law and for falsity based on an omission. *See Berkeley Heartlab*, 2017 WL 6015574, at *2 (stating that "the only reasonable inference" from 42 U.S.C. § 1320a-7b(g) "is that AKS violations are *per se* material"). Accordingly, because 42 U.S.C. § 1320a-7b(g) states that a claim caused by an AKS violation "constitutes a false or fraudulent claim" as a matter of law, it requires the courts to treat the question of materiality—just one element of that term—as resolved. *Arnstein*, 2019 WL 1245656, at *28 ("[F]or claims submitted after the effective date of the amendment, and where liability comes from . . . 31 U.S.C. § 3729(a)(1)(A), there is no need for an independent assessment of materiality. Congress has decreed these claims to be 'fraudulent' . . . ."). As the First Circuit pointed out when considering the same materiality issue, "[t]he statute's use of the term 'constitutes' would be meaningless if courts had to engage in a materiality analysis" even after satisfying 42 U.S.C. § 1320a-7b(g); once the claim "constitutes a false or fraudulent claim," materiality is established and need not be established again. *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019).

The defendants urge the court to treat 42 U.S.C. § 1320a-7b(g) the way *Escobar* directs courts to treat formal statements that particular rules are conditions of payment—as relevant but not determinative of materiality. The rule set forth in 42 U.S.C. § 1320a-7b(g), however, is not merely an assertion that AKS compliance is a condition of payment. Indeed, 42 U.S.C. § 1320a-7b(g) does not say anything about payment at all; it says, instead, that claims resulting from AKS

violations categorically satisfy the "false or fraudulent claim" requirement of the FCA. The designation of a rule as a condition of payment is a description of the relationship between the healthcare provider and the healthcare program, and it is only relevant to the FCA at all insofar as it happens to bear on the holistic question of materiality in an FCA case. Section 1320a-7b(g), however, takes an entirely different tack; it cites the FCA directly and requires that certain claims be treated as false or fraudulent, as that term of art is used in the FCA, as a matter of law. There is no room for a holistic inquiry when Congress has chosen instead to mandate a categorical rule.

In response to these arguments, the defendants draw the court's attention to *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89 (3d Cir. 2018), in which the Third Circuit stated, with limited analysis, that the materiality requirement of *Escobar* applied in an AKS-based FCA case. *Id.* at 98 n.8; *see also U.S. ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 414 (D.N.J. 2019) (assuming that *Escobar* applies to AKS-based FCA claims). Although the Third Circuit did not discuss the issue in depth, its conclusion appears to have been premised on the assumption, which the court supported with a citation to a district court opinion, that 42 U.S.C. § 1320a-7b(g) "clarif[ied], [but did] not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act." *Greenfield*, 880 F.3d at 95 (quoting *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F.Supp.2d 39, 52 (D. Mass. 2011)) (alterations in original). If 42 U.S.C. § 1320a-7b(g) truly had no effect on preexisting law, it would follow that the relationship between the AKS and FCA would remain the same as it was before the amendment—that is, the same relationship that exists between the FCA and any other statute, as governed by *Escobar*.

The cited district court case and its analysis, however, do not support so broad a conclusion. In that opinion, the District of Massachusetts examined the legislative history of the PPACA as it

related to 42 U.S.C. § 1320a-7b(g) and concluded that the provision was adopted because Congress had grown concerned, in light of then-recent litigation, that the nature of the relationship between the AKS and the FCA was in doubt in the courts. Congress therefore enacted the new provision to "ensure that all claims resulting from illegal kickbacks are 'false or fraudulent'" under the FCA. *Westmoreland*, 812 F.Supp.2d at 52 (quoting 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (Sen. Kaufman)). In other words, 42 U.S.C. § 1320a-7b(g) was enacted specifically to codify a particular relationship between the FCA and AKS that previously had been ambiguous or debatable. Later, *Escobar*, which was not based on the AKS and involved only a general construction of the FCA, resolved much of the outstanding ambiguity regarding how the FCA relates to other healthcare rules and statutes. That ambiguity, however, no longer existed with regard to the AKS, having been supplanted by the categorical rule set out in 42 U.S.C. § 1320a-7b(g). This court, therefore, does not share the Third Circuit's conclusion that *Escobar* can be applied to AKS-based claims merely because 42 U.S.C. § 1320a-7b(g) was, when enacted, ostensibly a "clarification." If anything, the PPACA "clarified" the issue of materiality, as it applies to an AKS-based FCA case, in one direction, and *Escobar* clarified it, for other types of claim, in a different direction. The general holding of *Escobar* cannot undo the more specific rule that Congress chose, just as, if Congress chose to enact an exception to *Escobar* after the Supreme Court's decision, that exception would carry the day.

The defendants could respond that, even if materiality is assumed for AKS-tainted claims under 31 U.S.C. § 3729(a)(1)(A), there is still room for dispute with regard to the Act's other relevant materiality requirement, the express materiality requirement of 31 U.S.C. § 3729(a)(1)(B). This argument is more difficult, and, frankly, the court has found it challenging to resolve the definition of "material" in the FCA with the definition of "false and fraudulent claim," as amended

by the PPACA. The most persuasive reading, however, is that the PPACA changed the nature of the court's inquiry under 31 U.S.C. § 3729(a)(1)(B) as well. Although the FCA's statutory definition of "material" refers to the "tendency to influence, or be capable of influencing . . . payment or receipt," 31 U.S.C.A. 3729(b)(4), that is simply not, as a purely grammatical matter, how the term is used in 31 U.S.C. § 3729(a)(1)(B) once one adds the PPACA's amendment to the definition of "false or fraudulent claim." What 31 U.S.C. § 3729(a)(1)(B) forbids, rather, is "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material"—not to payment—but "to a false or fraudulent claim." As the court has already held, "false or fraudulent claim" is a term of art that now categorically includes claims resulting from an AKS violation, regardless of materiality to any payment decision. It would be nonsensical to say that an AKS violation is nevertheless somehow not "material" to a false or fraudulent claim; one would be saying that an AKS violation is not material to itself.

The government is therefore correct that there is no contestable issue of materiality with regard to the government's AKS-based claims. Even if the defendants were permitted to engage in the discovery they have requested, and they uncovered the type of information that would support a finding of immateriality under *Escobar*—such as evidence of widespread toleration of deductible waivers for diabetes supplies in the Medicare program—it would have no bearing on the government's claims, because the PPACA has rendered all claims resulting from AKS violations "false or fraudulent claims" as a matter of law. Insofar as the production was ordered based on the premise that materiality might be factually contestable with regard to these claims, it was clear error.[3]

[3] As the court has already noted, the magistrate judge did not attempt to conclusively resolve the issue of whether AKS violations are *per se* material, on the ground that doing so would be premature. From a prudential perspective, there is nothing inherently wrong with that approach, particularly when the alternative is for the magistrate judge to rule on a potentially outcome-determinative legal question, despite

C. Materiality Regarding Government's Non-AKS FCA Theories

The defendants also argue that they should be permitted the discovery related to the Medicare program's treatment of other providers, in light of the government's stated intention to pursue two theories of liability that do not rely on the AKS and therefore do not implicate 42 U.S.C. § 1320a-7b(g). The government responds that, even in the absence of that provision, materiality is not disputed with regard to the remaining allegations.

With regard to billing for dead patients, the government's argument is persuasive. Indeed, it is not clear to the court that *Escobar* even provides the appropriate framework for such claims, because it is debatable whether they should even be viewed through the lens of implied false certification of compliance with a condition. One could argue that, when one bills for a product or service provided to a dead person, the biller is impliedly certifying that he is complying with the condition that the patient is alive. But there is a much simpler reason why such claims for payment are false or fraudulent: the biller is claiming to have provided a service or product to a person whom he did not, because that person was deceased—rendering the claim's identification of the recipient of the supplies facially false.

It is worth remembering that, while implied false certification cases are currently common under the FCA, they are not the only type of claim that the statute contemplates, and the caselaw governing implied certification therefore does not always furnish the appropriate framework for proceeding; acting otherwise would allow the relatively new concept of implied false certification to swallow the foundational concept of fraud. The defendants have not identified any reason, factual or legal, for doubting that the Medicare program only covers claims for diabetes supplies

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the fact that the parties have not consented to the resolution of dispositive motions by the magistrate judge. Now that the issue has been raised on a motion for review, however, that prudential consideration is gone, and it is the court's duty to determine whether the law supports the discovery awarded.

provided to actual, living Medicare beneficiaries. *See* 42 U.S.C. § 426 (limiting Medicare eligibility to certain classes of "individuals"). Indeed, the court is aware of no court that has even questioned the premise that, if scienter requirements are met, claims for care rendered to persons deceased at the time of care are fraudulent. *See Godinez v. Alere Inc.*, 272 F. Supp. 3d 201, 219 (D. Mass. 2017) (referring to claims for deceased beneficiaries as "fraudulent claims"); *Arriva Med. LLC v. United States Dep't of Health & Human Servs.*, 239 F. Supp. 3d 266, 274 (D.D.C. 2017) (referring to claims for deceased beneficiaries as "faulty billing"); *Stubbs v. Price*, 281 F. Supp. 3d 1360, 1369 (N.D. Ga. 2017) ("[A] provider who has submitted claims for payment for services rendered to deceased beneficiaries . . . is precisely the type of provider that Medicare has an obvious interest in removing from the program."). If a healthcare provider submits a claim stating that, for example, he provided a glucose meter to Medicare enrollee John Doe—but he did not actually provide it to John Doe, because John Doe was dead at the time and therefore incapable of possessing a glucose meter—then the claim was simply false about a fact inherently at the heart of the claim, with no implied certification required. There is no need for going down the road that *Escobar* paved for more ambiguous theories of falsity or fraud.

The five-year rule, in contrast, fits fairly neatly into the *Escobar* mold. While a claim for a service or product allegedly provided to an actually deceased enrollee includes an express falsity—the identification of the enrollee as the recipient—the same does not appear to be true with regard to the five-year rule; none of the parties in this case has suggested that claims to Medicare for glucose meters actually include an express certification that the patient has not received a meter in the last five years or that the five-year rule inherently goes to the heart of a Medicare claim. The alleged fraud, therefore, is of the type that *Escobar* would consider a misleading omission regarding compliance. There is, moreover, no statutory provision—like the PPACA AKS

amendment—that would take the issue of materiality out of the fact-intensive *Escobar* framework. Discovery into the Medicare program's actual enforcement of the five-year rule is therefore supported by *Escobar*, as long as the factors other than relevance do not outweigh the established relevance of the information sought.

The government nevertheless responds that the materiality of the five-year rule is undisputed, because (1) three Arriva executives testified, during the government's pre-intervention investigation, that their understanding was that Medicare does not pay claims filed in violation of the rule, and (2) Medicare claims data indicates that Arriva's claims were, in fact, frequently denied on that basis. While those facts are certainly relevant to materiality, the government has not established any basis for concluding that the pre-intervention testimony and Arriva-specific claims data take the issue totally out of the realm of dispute. Even if the cited evidence suggests that the five-year rule was being treated as material to Arriva's claims, it simply does not necessarily follow that Medicare was doing the same with regard to its other billers. It could, for example, be the case that Arriva was being singled out for enforcement, while other companies were not subject to the same scrutiny. It would significantly undermine the holding of *Escobar* if the government could manufacture an illusion of indisputable materiality simply by being extra strict ahead of time with whichever company the government wished to sue.

The possibility that Medicare was being lax with regard to the five-year rule for other companies may strike the government as unlikely, but it is not so wholly implausible as to defeat the forgiving relevance standard. The magistrate judge, therefore, did not clearly err when she concluded that evidence of Medicare's treatment of other suppliers was at least potentially discoverable. Insofar as she erred at all, it was in not qualifying her finding of relevance based on the fact that the discovery sought was relevant to only a subset of the government's claims.

D. Hardship

As a preliminary matter, the defendants argue that the government has waived most of its arguments regarding hardship because it did not originally provide the underlying evidence to the magistrate judge. Although the court finds the defendants' objection understandable, the court, in its discretion, declines to find waiver. There is no basis for concluding that the court is required, by the magistrate judge statute, 28 U.S.C. § 636, or any other provision of law, to refuse to consider the new evidence. To the contrary, the Sixth Circuit has held that a district court's "[i]nherent power" permits it, for good cause, to consider new evidence when considering a motion to review a magistrate judge's decision on a nondispositive issue. *Banner v. City of Flint*, 99 F. App'x 29, 35 (6th Cir. 2004) (citing *Chambers v. NASCO, Inc.*, 501 U.S. 32, 35 (1991)). Therefore, while the defendants may be correct that the court could, in its discretion, refuse to consider the new evidence as untimely introduced, the court is free to consider whether the interests of justice and efficiency support doing so. The court finds that the evidence offered by the government is relevant and persuasive and that it would harm the court's own interest in efficiency to simply analyze the defendants' requests for discovery as if the newly introduced evidence did not exist. The court, moreover, finds the failure to introduce the evidence earlier at least somewhat excusable in light of the limited written briefing before the magistrate judge.

Moreover, even if the court did not consider the new evidence of hardship, there would be reason to question the breadth of the defendants' requests. Those requests, taken literally, essentially call on the government to conduct an industry-wide audit of companies providing diabetes testing supplies to Medicare patients. Although *Escobar* made clear that a healthcare program's treatment of other billers is relevant to materiality in ordinary false certification cases, bare relevance does not negate risk that such discovery, if granted too broadly, would deteriorate

into "extended mini-trials" regarding each arguable comparator. *First Horizon Nat'l Corp. v. Houston Cas. Co*., No. 2:15-CV-2235-SHL-DKV, 2016 WL 5869580, at *9 (W.D. Tenn. Oct. 5, 2016). Limiting the government's production obligation to 25 companies might have lessened the burden somewhat, but 25 mini-trials' worth of discovery is still a great deal of discovery.

The court's narrowing of the finding of relevance, moreover, raises new questions about whether so broad an inquiry is necessary. According to the briefing, the government was able to document much of Arriva's history under the five-year rule through historical Medicare data. It presumably would be possible to do the same for other companies. Other documents or information may be legitimately discoverable as well, but this court finds it likely that a government review related to the five-year rule may not need to be as broad as, for example, an audit regarding AKS compliance, which could implicate issues far more complicated than the distance of time between two dates.

To the court's knowledge, there has not yet been any effort, between the parties, to craft a discovery plan that assumes relevance under *Escobar* solely with regard to the five-year rule, and the government has expressed a willingness, if necessary, to work with the defendants to narrow the information sought in a subject-specific manner. (Docket No. 159 at 21.) The court will, accordingly, order the parties to begin a new meet-and-confer process based on the limitations set forth in this Memorandum.

If the parties are unable to come to an agreement, they can, of course, begin the discovery dispute process anew. Given the substantial delay between the filing of the initial Complaint and the government's intervention decision, however—which has led to these claims' being among the oldest active claims on the court's docket—the parties are strongly encouraged to try to reach an expeditious agreement that reflects all parties' legitimate interests and concerns. The defendants

are encouraged to keep in mind that their requests should be tailored to the specific issues of materiality raised by this case and that, while *Escobar* addressed relevance, nothing in the case negated the importance of weighing relevance against hardship; the government, for its part, is encouraged to remember that, given that it chose to spend over five years' worth of resources on its one-sided investigation, it bears a heavy burden in arguing that, now that the defendants have a turn, the government's means are too scant to cooperate.

IV. CONCLUSION

For the foregoing reasons, the Motion for Review filed by the United States (Docket No. 158) is hereby **GRANTED** in part and **DENIED** in part. The magistrate judge's Order of May 18, 2020 (Docket No. 154) is **VACATED** in part, and the parties are hereby **ORDERED** to meet and confer in an attempt to come to an agreed scope of production in light of the court's Memorandum.

It is so **ORDERED**.

ALETA A. TRAUGER
United States District Judge